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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/723,197

Applicant(s)

RODGERS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election with traverse of SEQ ID NO:4 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the search can be made without burden since the search for the claimed scopes would extensively overlap, e.g., SEQ ID NO: 5, 6, 8, 9, 10 and 11 are contained in the SEQ ID NO:4. This is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that there is no additional search burden. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803. The peptide of SEQ ID Nos: 5, 6, 8, 9, 10 and 11 are fragments of SEQ ID NO:4, however, each peptide has different amino acid sequence, exhibits different chemical and physical property, and produces different effect, thus each peptide is patentably distinct. For example, the angiotensin II (AII) fragment, AII (1-7) (SEQ ID NO:4), which lacks a Phe residue in AII, acts through a receptor that is distinct from the receptors that AII binds, and AII (1-7) often opposes the actions of AII (page 13, lines 7-13 of the specification). Furthermore, coexamination of each of the additional sequences would require search of sequences unnecessary for the examination of the elected sequence, thus, coexamination of each of these inventions would require a serious additional burden of search. Therefore, claims 1-34 with SEQ ID NO:4 are examined.

The requirement is still deemed proper and is therefore made FINAL.

***Informalities***

The disclosure is objected to because of the following informalities:

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2. The specification uses the brackets [...] in the text, e.g., "Asp-Arg-Val-Tyr-Ile-His-Pro-Phe [SEQ ID NO:1]" at page 10, line 9. Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. Applicant has used "[...]" in such a manner that appears the instant brackets would indicate deleted material and is thus, confusing as to whether the "SEQ ID NO:1" in the bracket would be included in the specification.

Appropriate correction is required.

### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 7, 25, 26, 28, 31-33, 35-38, 41-43 and 46-48 of copending application No. 09/307,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-29 in the instant application disclose an improved method for chemotherapy in a human patient, comprising administering an effective amount of an active agent comprising a sequence of formula I ( $R^1-R^2-R^3-R^4-R^5-R^6-R^7-R^8$ ) which includes SEQ ID NO:4 for treating or preventing

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chemotherapy side effects; and a pharmaceutical composition comprising the active agent and a pharmaceutically acceptable carrier. This is obvious in view of claims 6, 7, 25, 26, 28, 31-33, 35-38, 41-43 and 46-48 of copending application which discloses a method for increasing white blood cell survival following chemotherapy comprising administering an effective amount of an active agent comprising a sequence of Asp-Arg-R1-R2-Ile-His-Pro-R3 (SEQ ID NO:42) or formula I ( $R^1-R^2-R^3-R^4-R^5-R^6-R^7-R^8$ ) which includes SEQ ID NO:4; and a pharmaceutical composition comprising the active agent, a cytotoxic agent and a pharmaceutically acceptable carrier, where the limitations are also cited in the instant application. Thus, claims 1-29 in present application and claims 6, 7, 25, 26, 28, 31-33, 35-38, 41-43 and 46-48 of copending application are obvious variations of a method for treating chemotherapy side effects in a patient comprising administering an effective amount of an active agent comprising a sequence of formula I ( $R^1-R^2-R^3-R^4-R^5-R^6-R^7-R^8$ ) which includes SEQ ID NO:4, and a pharmaceutical composition comprising the active agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-34 are indefinite because the claim contains non-elected sequences. Claims 2-34 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

5. Claims 1-27 are indefinite because they lack essential steps as claimed in the process of treating or preventing chemotherapy side effects. The omitted steps are the method of administration and the outcome of the treatment. Claims 2-27 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

6. Claim 6, for example, is indefinite because of the use of the term “consists essentially of”. The term “consists essentially of” renders the claim indefinite, it is unclear what difference is between the active agent “consists essentially of” a sequence of at least 3 contiguous amino acids of groups  $R^1$ - $R^8$  in the sequences of formula I and the active agent “comprises” the same. See also claims 7-10, 13, 14 and 18.

7. Claim 20, for example, is indefinite because of the use of the term “between about 2.5  $\mu\text{g/kg/day}$  and about 100  $\mu\text{g/kg/day}$ ”. The term “between about 2.5  $\mu\text{g/kg/day}$  and about 100  $\mu\text{g/kg/day}$ ” renders the claim indefinite, it is unclear the dosage is in the range of 2.5 to 100  $\mu\text{g/kg/day}$  as to “between.....about...”, or, below 2.5  $\mu\text{g/kg/day}$  as to “about”. Deletion of “about” in the term “between about” is suggested. See also claims 21 and 28.

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***Conclusion***

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

*Karen Cochrane Carlson Ph.D.*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

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July 19, 2002